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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,012	03/05/2002	Liu-Ying Luo	11757.67USU1	7644

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EXAMINER	
NICKOL, GARY B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,012	LUO ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-5, drawn to isolated nucleic acids, vectors, host cells and a method for preparing a polypeptide, classified in class 536, subclass 23.1, 23.5; class 435, subclasses 320.1, 325, 69.1.

   (Upon election of Group 1, applicant must elect *one* nucleic acid from SEQ ID NOs: 1-8 as each nucleic acid is an independent group, not a species)

2. Claim 6, drawn to an isolated protein, classified in class 530, subclass 300,350.

   (Upon election of Group 2, applicant must elect *one* protein encoded by one of SEQ ID NOs: 1-8 as each encoded product is an independent group, not a species)

3. Claims 7-8, drawn to isolated antibodies, classified in class 530, subclass 387.1.

   (Upon election of Group 3, applicant must elect *one* antibody that binds to a protein encoded by one of SEQ ID NOs: 1-8 as each antibody is an independent group, not a species)

4. Claims 9-10, drawn to a method for detecting a nucleic acid molecule in a biological sample, classified in class 435, subclass 6.

(Upon election of Group 4, applicant must elect *one* nucleic acid from SEQ ID NOs: 1-8 as each nucleic acid is an independent group, not a species)

5. Claims 11-12, drawn to a method of diagnosing and monitoring cancer mediated by a tumor associated protein by determining the presence of a *nucleic acid* molecule that encodes ONE polypeptide, classified in class 424, subclass 9.1.

6. Claims 11-12, drawn to a method of diagnosing and monitoring cancer mediated by a tumor associated protein by determining the presence of ONE *polypeptide*, classified in class 436, subclass 64; class 435, subclass 7.23.

7. Claims 13-14, drawn to a method for preventing or treating a condition mediated by a tumor associated protein comprising administering an effective amount of an antibody specific for ONE tumor associated protein, classified in class 424, subclass 130.1.

8. Claims 15, 17-20, drawn to a vaccine to prevent and/or treat cancer comprising a tumor associated protein and methods of use thereof, classified in class 424, subclass 184.1.

9. Claim 16, drawn to a method to prevent or to treat cancer in subjects who have a tumor associated protein on their cells comprising administer a "vaccine" for stimulating or enhancing in the subjects antibodies directed against ONE tumor associate protein, classified in class 514, subclass 1.

(Upon election of any one of Groups 5, 6, 7, 8, or 9 above, applicant must elect ONE of the following tumor associated polypeptides, as each polypeptide/nucleic acid independently imparts a distinct method, not a species: Genbank AJ271448, Genbank AK001674, Genbank NM-005801, Genbank AL359945, MIL1 protein, NM-015367, Genbank X70326, Genbank AF0867763, Genbank NM-003628, or a polypeptide encoded by any ONE of SEQ ID NOs: 1-8.)

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups 1-3, include isolated nucleic acid molecules, recombinant polypeptides, and isolated antibodies; all of which represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Each molecule is a distinct chemical structure that has different chemical entities and or different structures. The products are also classified differently necessitating different searches in the literatures. Further,

upon election of any one of Groups 1-3, applicants are required to choose one of the eight distinct nucleic acids referred to as SEQ ID NOs: 1-8. This requirement is necessary because there is a high burden of search that accompanies both the search and examination of one nucleic acid and amino acid sequence. Currently, there are approximately eight different databases that accompany the results of a search of one discrete amino acid or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of eight different sequences, the products and fragments they encode, and the potential epitopes they contain, would require extensive searching and review.

The inventions of Groups 4-9 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. For example, Group 4, drawn to a method of detecting a particular nucleic acid sequence, differs from Group 5 in that Group 5 requires different response variables and criteria for success since it is drawn to diagnosing and or monitoring for the presence of cancer. Further, Group 5 and Group 6 are materially distinct methods, which involve different reagents; one is drawn to detecting nucleic acids, while the other is drawn to detecting and or observing the polypeptide. Further, all of the method groups are classified differently requiring different searches and considerations in the literature. Further, upon election of any one of Groups 4-9, applicants are required to choose one of the eight distinct nucleic acids referred to as SEQ ID NOs: 1-8 and or one of the tumor associated polypeptides. This requirement is necessary because there is a high burden of search that accompanies both the search and examination of one nucleic acid and amino acid sequence.

The invention of Group 1 and the method of Groups 4 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid products as claimed can be used in materially different processes such as affinity chromatography, methods of hybridization, and methods of detecting or monitoring cancer.

The invention of Group 2 and the method of Group 6 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the tumor associated polypeptide products as claimed can be used in materially different processes such as affinity chromatography, methods of detecting or monitoring cancer, and in vaccine formulations for stimulating antibody responses.

The invention of Group 3 and the method of Group 7 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that

product [see *MPEP* § **806.05(h)**]. In the instant case the antibody products as claimed can be used in materially different processes such as affinity chromatography, methods of detecting or monitoring tumor associated polypeptides, and methods of treating cancer.

The invention of Groups 1-3 and the method of Group 9 are not at all related because the products of Groups 1-3 to not appear to be used in the method of Group 9.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may

be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN
March 11, 2004

Gary B Nickol

GARY NICKOL
PRIMARY EXAMINER